Opioid Use Guidelines for Chronic Pain Treatment

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Faculty Disclosure

Dr. Levy and Dr. Feinberg have both attested that they have nothing to disclose.

Introduction

- Current climate
  - California Work Comp Institute data
  - State Compensation Insurance Fund
  - National News
- Describe what providers are not doing which can lead to problems
  - Discuss WOEMA opioid guidance document
- Implementing proper practices
- Frequently asked questions
Experiences with Pain

- Affects 116 Million Americans
  - More than heart disease, diabetes and cancer combined
  - Indirect/direct medical expenses US $560-$630 Billion/year
  - #1 reason people out of work
- More than 300 million prescriptions for analgesics (125 million for Vicodin) are written each year for pain

Prescription Drug Abuse

- Youths
  - Fastest growing prescription abuse group
  - Obtain prescription opioids from family - friends
- Elderly
  - Includes pain patients who abuse opiate meds
  - Users typically have co-morbid medical and psychiatric conditions
- Baby Boomers
  - Used drugs in the 1960’s & 1970’s

Sources of Prescription Opioid Abuse

- 70% of prescription abuse of opioids is obtained from a friend or relative and 18% are from a single HCP
## Table 3

<table>
<thead>
<tr>
<th>Prescriber Type</th>
<th>Top 5 Outcomes</th>
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<tbody>
<tr>
<td>Total</td>
<td>59,789</td>
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*Top outcomes include approximately 30% (physicians), or the top 1 (physicians).*
State Compensation Insurance Fund (SCIF)

- Recently SCIF proposed several changes to their MPN
- Opioids prescribed for more than 60 days require pre-authorization

Definition of Terms

- **Addiction**
  - A primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations
  - Behavioral characteristics include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, craving

- **Pseudoaddiction**
  - Syndrome of abnormal behavior resulting from undertreatment of pain that is misidentified by the clinician as inappropriate drug-seeking behavior
  - Behavior ceases when adequate pain relief is provided
  - Not a diagnosis, rather, a description of the clinical intention


Definition of Terms

- **Tolerance:**
  - Loss of a drug’s effects over time or the need to increase the dose to maintain the effect

- **Withdrawal:**
  - A syndrome that occurs due to the cessation or reduction of prolonged use of a drug
  - Acute opioid withdrawal is characterized by dysphoria, nausea or vomiting, muscle aches, lacrimation, rhinorrhea, pupillary dilation, diarrhea, yawning, fever, or insomnia
Federation of State Medical Boards

- Pain management is important and integral to the practice of medicine
- Use of opioids may be necessary for pain relief
- Use of opioids for other than a legitimate medical purpose poses a threat to the individual and society
- Physicians have a responsibility to minimize the potential for abuse and diversion
- Physicians may deviate from the recommended treatment steps based on good cause
- Not meant to constrain or dictate medical decision-making

FSMB Model Policy for the Use of Controlled Substances for the Treatment of Pain @ http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf

Safely Managing Opioids in Chronic Pain

- Are opioids appropriate – for which patients
  - Assessment of the benefit and the risk of likelihood of abuse, misuse, or addiction
- Informed consent and agreement including
  - Goals of treatment (benefits)
  - Expectations (physician and patient)
  - Risks and alternatives
- Which opioids to use
- Monitoring the patient including UDT
- Expect and treat side-effects
- How long to treat

Common Side-Effects

- Constipation
- Nausea
- Vomiting
- Somnolence
- Asthenia including fatigue
- Dizziness
Opioid Agreement

- You will not obtain any other prescription for controlled medication from another source/physician
- Our staff may communicate with any pharmacy or health care professional regarding your medications
- Medication will only be refilled during regular office hours
- Lost narcotic medication cannot be replaced
- Stolen narcotic medication MAY be replaced provided you obtain a police report and are seen in the office

Safely Managing Opioids in Chronic Pain

- Initiation and Titration of Chronic Opioid Therapy
  - Treatment individualized
  - Always a trial
- Monitoring patients on opioids
  - Level of function
  - Progress toward predetermined goals
  - Presence of adverse events
  - Compliance (or lack of)
- Co-Interventions
  - Psychological and behavioral approaches – CBT
  - Functional restoration physical rehabilitation

Risk Factors for Abuse

- Personal or family history of substance abuse
- History of adverse childhood experiences (ACE)
  - Neglect
  - Physical, emotional, sexual abuse
- Mental illness
- Psychological stress (chemical coping)
Primary Risk Factor for Misuse

- Uncontrolled or inadequately treated pain

Identifying at Risk Patients

- Predictive tools
- Aberrant behaviors
- Urine drug testing
- Prescription monitoring programs
- Severity and duration of pain
- Pharmacist communication
- Family and friends
- Patients

Signs of Potential Abuse and Diversion

- Request appointment toward end-of-office hours
- Arrive without appointment
- Telephone/arrive after office hours when staff are anxious to leave
- Reluctant to have thorough physical exam, diagnostic tests, or referrals
- Fail to keep appointments
- Unwilling to provide past medical records or names of HCPs
- Unusual stories
- However, emergencies happen: not every person in a hurry is an abuser/diverter
Risk Assessment Tools

- **ORT**: Opioid Risk Tool
- **SOAPP**: Screener and Opioid Assessment for Patients with Pain
- **DIRE**: Diagnosis, Intractability, Risk, Efficacy
- **COMM**: Current Opioid Misuse Measure
- **PMQ**: Pain Medication Questionnaire
- **DAST-10**: Drug Abuse Screening Test

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Risk Assessment Tools

- **ORT, SOAPP & DIRE**
  - Best assess abuse potential among those being considered for long-term opioid therapy
- **COMM & PMQ**
  - Characterize degree of medication misuse or aberrant behavior once opioids are started
- **DAST-10 & PMQ**
  - More suitable for assessing current alcohol and/or drug abuse than potential for such abuse


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Stratifying the Risk

<table>
<thead>
<tr>
<th>Low Risk</th>
<th>Moderate Risk</th>
<th>High Risk</th>
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<tbody>
<tr>
<td>No past/current history of substance abuse</td>
<td>History of treated substance abuse</td>
<td>Active substance abuse</td>
</tr>
<tr>
<td>Noncontributory family history of substance abuse</td>
<td>Significant family history of substance abuse</td>
<td>Active addiction</td>
</tr>
<tr>
<td>No major or untreated psychological disorder</td>
<td>Past/morbid psychological disorder</td>
<td>Major untreated psychological disorder</td>
</tr>
<tr>
<td>Not actively addicted</td>
<td></td>
<td>Significant risk to self and practitioner</td>
</tr>
</tbody>
</table>
High Risk Patients

- Refer to Pain Specialist or addictionologist

Opioid Policies

- Federal laws
- State laws
- Regulatory guidelines
- Policy statements
Risk Evaluation and Mitigation Strategies (REMS)

- The Food and Drug Administration Amendments Act of 2007 gave FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks.

Federal Regulations

- Must have physician-patient relationship
- Must have a chart
- Documentation of each Rx
  - Document reason for early refills
  - Document reason for any change in dosage
- Document expectation of treatment's effect
- Documentation of diagnosis causing pain

The Rules!

- Cannot Rx Schedule II or III for family members
- Can provide samples of unscheduled drugs for family, but MUST document in a medical record
- Cannot Rx for anyone in sexual relationship,
  EVER
- Cannot Rx opioids for yourself, EVER
- Cannot Rx opioids to anyone (including friends) if you have not documented their H& P and have a current chart on file
The 4 A’s

- Analgesia
- Activities of Daily Living
- Adverse Events
- Aberrant Drug-Taking Behaviors

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Strategy for Prescribing Opioids

- Careful assessment and formation of an appropriate differential diagnosis
- Psychological assessment including risk of addictive disorders
- Informed consent
- Treatment agreement
- Appropriate trial of opioid therapy +/- adjunctive medications
- Assessment and reassessment of pain and level of function
- Regularly assess the 4 A’s of pain medicine (Analgesia, Activities, Adverse Effects and Aberrant Behavior)
- Steps to reduce risk
- Thorough documentation in the medical records

Adapted from Gourlay DL, Heit HA et al Pain Med. 2005; 6 107-12

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WOEMA Guidance Document
Urine Drug Testing

- **Advantages**
  - Can confirm that prescribed drug is taken and that other drugs are not
  - Makes a strong statement potentially useful in monitoring

- **Disadvantages**
  - Cannot confirm that the proper dose is taken
  - Can be misinterpreted
  - Can be stigmatizing

- **When to Test?**

Urine Drug Testing (UDT)

- Initial testing (lab or POC) done with class-specific immunoassay drug panels
  - Typically do not identify individual drugs within a class (rapid results, not quantitative, low specificity)

- Followed by a technique such as GC/MS
  - To identify or confirm the presence or absence of a specific drug and/or its metabolites


UDT

- Opiate immunoassays detect morphine and codeine
  - Do not detect synthetic opioids such as Methadone or Fentanyl
  - Do not reliably detect semisynthetic opioids such as Oxycodone, Hydrocodone, buprenorphine, Hydromorphone

- GC/MS will identify these medications
Conclusions

- Use of opioids may be appropriate
  - Pathology that fits the problem
  - Improved level of function and increased ADLs
  - Decreased pain
  - Manageable side effects
- Balanced multimodal care
  - Use of opioids as part of complete pain care
  - Anticipation and management of side effects
- Maintain standard of care

Frequently Asked Questions

1) If you’re treating a patient with opioids and after 90 days they refuse to sign a pain agreement, how do you proceed?

2) If a patient claims they are taking a medication and a random drug test fails to demonstrate the substance, do you stop prescribing immediately?
Frequently Asked Questions

3) If a person were to be diverting their medications but takes a few tablets on the way to the office appointment, would this show up in their urine screen?

Frequently Asked Questions

4) Do you screen all patients prior to initiating opioids? If so, how do you do so?

Frequently Asked Questions

5) Can you spot patients likely to be diverting/abusing based on appearance and behavior?
Frequently Asked Questions

6) How do you measure functional improvement while following a patient on opioids?

Frequently Asked Questions

7) If you have a patient who is not showing any functional improvement while on opioids and in fact is having worsening pain, how do you handle this?

Frequently Asked Questions

8) Is there a role for medications like Actiq, Lyrica, Cymbalta for treating axial low back pain?
Frequently Asked Questions

9) I have had significant difficulty at times getting an authorization for an evaluation by a chronic pain specialist. Would you have recommendations of what the essential documentation components are that would best justify why a consultation is medically necessary?

References

- Managing Chronic Pain with Opioids in Primary Care, 2nd Edition
  - Managing Chronic Pain with Opioids in Primary Care, 2nd Edition
  - Guideline For the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain by The American Pain Society in Conjunction with The American Academy of Pain Medicine
  - Responsible Opioid Prescribing: A Physician’s Guide by Scott M. Fishman, MD, Federation of State Medical Boards, 2007
  - Opioid Prescribing Toolkit by Nathaniel Katz, MD, Oxford University Press, 2011
  - Opioid Clinical Management Guide by CARES Alliance

Internet Resources

- General Pain Sites
  - painACTION – http://www.painaction.com
- Laws or Legal Issues Regarding Opioid Treatment
  - Federation of State Medical Boards – http://www.fsmb.org
  - Drug Enforcement Administration, Office of Diversion Control - http://www.deadiversion.usdoj.gov
  - The Legal Side of Pain – http://www.logisticsofpain.com
  - University of Wisconsin Pain & Policy Studies Group – http://www.painpolicy.wisc.edu
- Risk Assessment Tools
- Resources for Chronic Pain Patients
  - American Chronic Pain Association – http://www.theacpa.org
Questions?

- For any additional information feel free to contact us at
- StevenFeinberg@hotmail.com
- Scott.Levy@kp.org

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